

REMARKS

I. Attorney Docket Number

Applicants note that the attorney docket number has changed from 08806.0176-00000 to 02508.0119-00000.

II. Status of the Claims

Claim 2 was cancelled previously. Claims 3, 5 and 18 have been cancelled in this paper without prejudice or disclaimer. Applicants reserve the right to pursue the subject matter from any of the cancelled claims in one or more continuing applications. Claim 31 has been newly added. After entering this amendment, claims 1, 4, 6-17 and 19-31 will be pending, with claims 12-16 and 26-30 withdrawn from consideration as being directed to non-elected subject matter. Thus, claims 1, 4, 6-11, 17, 19-25, and 31 will be under consideration. The claim amendments are discussed in more detail in the sections below.

III. Statement under 37 C.F.R. § 1.133 regarding interview with the Examiner

Applicants thank Examiner Sean Everett for the helpful in-person interview conducted on March 18, 2010. Applicants' representatives discussed with the Examiner the remaining rejections in the instant application, the cited art, and possible amendments to the claims that appear to overcome the rejections of record. Applicants have amended the claims in this response according to the discussions had during the interview.

IV. Amendments to the Claims

Claim 1 has been amended to replace "contents" with "solution." This amendment finds support throughout the specification, for example, on page 4, lines 22-31. Claim 1 has also been amended to add "wherein the terminally sterilized solution contains low levels of cytotoxic degradation products." This amendment finds support throughout the specification, for example, on page 10, lines 22-27, and page 11, lines 28-34. Claim 1 has also been amended to add "and wherein the one or more acetylated or deacetylated amino sugars is N-acetylglucosamine." This amendment finds support throughout the specification, for example, on page 8, lines 24-31, and page 9, line 36, to page 10, line 7, and original claim 5. Claims 4, 7, 9, 19-20, and 24 have been amended to be consistent with the amendments to claim 1. These amendments find support at least in the same portions of the application as the amendment of claim 1. Claim 7 has also been amended to replace "the other/others" with "other compartments." "Compartments" has antecedent basis in claim 1, from which claim 7 depends. Claim 31 has been newly added. This new claim finds support in the specification similarly as claim 1, and including in Figure 1 and on page 6, lines 9-17. Thus, all claim amendments are fully supported by the specification and they do not add any new matter.

V. Rejections under 35 U.S.C. § 112

Claims 1, 3-11 and 17-25 are rejected under 35 U.S.C. § 112, second paragraph, as being "indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention." Office Action, page 2.

Specifically, the Office contends that there is insufficient antecedent basis for the phrase "the contents" in line 6 of claim 1. Applicants have amended claim 1 to replace "the contents" with "the solution." "The solution" has antecedent basis in line 4 of claim 1.

The Office further contends that there is insufficient antecedent basis for the phrase "the other/others" in line 2 of claim 7. Applicants have amended claim 7 to replace "the other/others" with "other compartments." "Compartments" has antecedent basis in claim 1, from which claim 7 depends.

The Office further contends that there is insufficient antecedent basis for the phrase "the terminally sterilized solution" in line 3 of claim 7. However, this phrase has antecedent basis in amended claim 1, from which claim 7 depends. Therefore no further amendment of claim 7 is required.

The Office further contends that there is insufficient antecedent basis for the phrase "said compartments" in line 3 of claim 10. However, this phrase has antecedent basis in amended claim 1, from which claim 10 depends. Therefore no further amendment of claim 10 is required.

In view of these amendments and remarks, the instant claims are not indefinite. Thus, Applicants respectfully request withdrawal of the rejections under 35 U.S.C. §112, second paragraph

VI. Claim Objections

The Office objected to claim 11 because line 1 of claim 11 fails to recite the claim from which it depends. Office Action, page 3. In response, Applicants have amended claim 11 to indicate its dependency from claim 1.

The Office further objected to claim 17 because claim 17 depends from cancelled claim 2. *Id.* In response, Applicants have amended claim 17 to indicate its dependency from claim 1.

In view of these amendments and remarks, the claim objections have been fully addressed. Thus, Applicants respectfully request withdrawal of the objections.

VII. Rejections under 35 U.S.C. § 103(a)

Claims 1, 3-11 and 17-25 are rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,536,469 to Jonsson et al. ("*Jonsson*") in view of Breborowicz et al., "Replacement of Glucose with N-Acetylglucosamine in Peritoneal Dialysis Fluid - Experimental Study in Rats," *Peritoneal Dialysis International*, 21(Supplement 3): S365-S367 (2001) ("*Breborowicz*"). Office Action, pages 3-6.

According to the Office, *Jonsson* discloses a sterile medical solution containing glucose or glucose-like compounds for peritoneal dialysis. *Id.* at page 4. The Office acknowledges, however, that *Jonsson* neither discloses "a medical solution containing one or more acetylated or deacetylated amino sugars," such as N-acetylglucosamine, nor "the preparation of a final medical solution wherein the pH is 7.4." *Id.* A solution comprising N-acetylglucosamine is a limitation shared by all claims under consideration, while a finally prepared medical solution wherein the pH is 7.4 is a limitation of claim 23.

The Office contends that *Breborowicz* makes up for these deficiencies of *Jonsson* by "teach[ing] partial replacement of glucose with N-acetylglucosamine (NAG) in peritoneal dialysis fluid results in advantageous preservation of the peritoneal membrane." *Id.* at pages 4-5. The Office concludes that "[o]ne of ordinary skill in the art would be motivated to combine *Jonsson* et al. in view of *Breborowicz* et al. because

Breborowicz teaches it is advantageous to partially replace glucose with N-acetylglucosamine (NAG)." *Id.* at page 5. The Office further concludes that "[o]ne of ordinary skill in the art would be motivated to optimize the final medical solution wherein pH is 7.4 because *Jonsson et al.* teaches the final peritoneal dialysis solution optimized at a pH between 6.5 and 7.5." *Id.* at pages 5-6.

In response to Applicants' arguments presented in the amendment filed on January 8, 2010, the Office states that Applicants' arguments were fully considered but were not found persuasive. *Id.* at pages 6-10. Applicants respectfully disagree and traverse for the reasons discussed during the interview with the Examiner on March 18, 2010 (see above).

Therefore, in an effort to advance prosecution of the instant application, Applicants have amended the claims according to the discussion with the Examiner at the interview. Specifically, Applicants have amended claim 1 to include the amino sugar N-acetylglucosamine (NAG) and to add limitations that link together the claimed pH of 2.5-3.5 with the resulting low toxicity. As discussed at the interview, the state of the prior art at the time the instant application was filed taught away from sterilizing NAG-containing solutions at an acidic pH. For example, *Rovati* (U.S. Patent No. 3,697,652) teaches that acetylated amino sugars can be heat-sterilized in solution at a recommended pH of 8.2-8.3 but warns against changing the pH of the solution because it was found to have a detrimental effect. See, e.g., Response filed January 8, 2010, at p. 7-14.

In view of these amendments and remarks, the pending claims 1, 4, 6-11, 17, 19-25, and 31 are patentable over the cited art. Thus, Applicants respectfully request that the rejections under 35 U.S.C. §103(a) be withdrawn.

VIII. Conclusion

In view of the above amendments and remarks, the pending claims are now in condition for allowance. Applicants therefore request reconsideration of the application and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to Deposit Account No. 06-0916.

Respectfully submitted,

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By: _____



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